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09/784,232	02/15/2001	Nicholas L. Abbott	032026:0502	2504

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 06/06/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/784,232

Applicant(s)

ABBOTT ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/03 has been entered.

Applicant's amendment filed 2/27/03 in Paper No. 15 is acknowledged and entered. Claims 17-63 are canceled by the amendment. Claim 1 is amended by the amendment.

2. Claims 1 and 3-16 are pending.

***Drawings***

3. The corrected or substitute drawings were received on 7/8/02. These drawings are acceptable.

***Withdrawn Rejections***

4. The previous rejections under 35 USC 102(e) as being anticipated by Abbott et al. (US Patent 6,277,489 B1) for claims 1, 3-6, and 14 are have been withdrawn in view of applicant's amendments of claim 1.

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5. The previous rejections under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter for claims 1, 3-7 and 14 have been withdrawn in view of applicant's amendments of claim 1.

6. The previous rejections under 35 USC 103(a) as being obvious over Abbott et al. (US Patent 6,284,197 B1) in view of Leavitt et al. (US Patent 5,712,103) for claims 8-9 are have been withdrawn in view of applicant's amendments of claim 1.

7. The previous rejections under 35 USC 103(a) as being obvious over Abbott et al. (US Patent 6,284,197 B1) for claims 10-13 and 15 are have been withdrawn in view of applicant's amendments of claim 1.

8. The previous rejections under 35 USC 103(a) as being obvious over Abbott et al. (US Patent 6,284,197 B1) in view of Leavitt et al. (US Patent 5,712,103) as applied to claims 8-9 above, and further in view of Chagnon et al. (US Patent 4,628,037) for claims 17-18 are have been withdrawn in view of applicant's cancellation of claim 17-18.

9. Claims 1 and 3-16 are treated on the merit in this Office Action.

***New Rejections – Necessitated by Amendment***

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Clarification is needed for the method step (b) with regard to claim 16 for “treating the surface of the detection region”. The method step (b) recites, “treating the surface of the detection region to provide a layer that blocks nonspecific binding of the pathogen to the surface **and** that includes a binding agent that specifically binds the selected pathogen to be detected” and step (d) “wherein the presence of the selected pathogen bound to the binding agent and at least partially occupying the depressions.” Claim 16 recites “wherein substantially all the binding agent is located in the depressions of the detection region.” The limitation of claim 16 contradicts the limitation of claim 1 (b) and (d) in which the “layer” on the surface is a mixture of “non-specific binding agent” (BSA) and “binding agent” (IgG) as shown in figure 3 of the specification.

b) The term “substantially” in claim 16 is a relative term, which renders the claim indefinite. The term “substantially” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 1 and 3-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbott et al. (US Patent 6,284,197 B1).

The applied reference has common inventors (Nicholas L. Abbott and Justin J. Skaife) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Abbott et al. disclose a method for detecting an analyte (col. 5, lines 60-67 to col. 6, lines 1-3; col. 13, lines 18-25). The method comprise of the analyte (pathogen) first interacts with the recognition moiety (binding agents) and the mesogenic layer (liquid crystal) is introduced in its isotropic phase. The mesogenic layer is subsequently cooled to form the liquid crystalline phase. The presence of tie analyte within regions of the mesogenic layer will disturb the equilibrium

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between the nematic and isotropic phases leading to different rates and magnitudes of nucleation at those sites. The differences between the nematic and isotropic regions are clearly detectable (col. 32, lines 21-29) (refers to steps (c) and (d) of claim 1). The analyte is a biomolecule (pathogen) (col. 29, line 11-15). The recognition moieties bind to, or otherwise interact with, the analyte of interest (col. 26, lines 21-23). The recognition moiety is a biomolecule wherein the biomolecule is a protein, antibody, peptide, nucleic acid (e.g., single nucleotides or nucleosides, oligo nucleotides, polynucleotides and single- and higher-stranded nucleic acids), biotin or a combination thereof (col. 26, line 30-36) (refers to claims 14). The recognition moiety is attached to the surface of the substrate by any of a number of interaction types (col. 13, lines 41-42) and pretreated with BSA (bovine serum albumin) (col. 7, lines 46-54) (refers to steps (a) and (b) of claim 1 and claim 8-9). The substrate can be both simple planar and also more complex geometries (e.g., curved, cylindrical, sinusoidal) for example a TEM grid (col. 13, lines 32-39) (depressions having width and depth). The recognition moiety can be attached to the spaces between the mesh members (i.e., in wells) and the mesogenic layer is floated on the top of the substrate (refers to claim 16). The size and complexity of the pattern on the substrate is limited only by the resolution of the technique utilized and the purpose for which the pattern is intended (col. 17, line 7-27). The patterning of the substrate can have features of about 1  $\mu\text{m}$  - 200 nm are possible (refers to claims 10-13 and 15). The substrate materials include, but are not limited to, inorganic crystals, inorganic glasses, inorganic oxides, metals, organic polymers and combinations thereof (col. 14, lines 56-58). Wherein the substrate is a metal film such as a gold film, the group, which reacts with the metal surface, comprises a thiol, sulfide or disulfide (col. 22, lines 4-38) (refers to claim 3-4). Wherein the substrate is an organic polymer, the organic

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polymers include polydimethylsiloxane, polyethylene, polyacrylonitrile, cellulosic materials, polycarbonates, polystyrenes, polycyanoacrylate and polyvinyl pyridinium (col. 15, lines 66-67 to col. 16, lines 1-14) (refers to claims 5-7). Therefore, Abbott et al. anticipates the presently claimed method.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1, 8-9, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alberti et al. (*Infection and Immunity*, 1996, 64(11):4726-4732) and Woolverton et al. (US Patent 6,171,802 B1).



Albertí et al. disclose a method of detection *Klebsiella pneumoniae*, which is a nosocomial pathogen (pg. 4726, left col., lines 1-4). The method comprise of coating the microtiter plates wells (substrate having width and depth) with BSA ("blocking agent") and "binding agent" (pg. 4727, right col., lines 11-22). The pathogen binding is detected by a phosphate labeled anti-antigen.

The method of Albertí et al. does not expressly disclose that the detection of pathogen binding by liquid crystal material.

Woolverton et al. disclosed a method wherein a liquid crystal will amplify the distortion caused when a ligand binds to a receptor (col. 4, lines 61-62). The binding of a ligand, such as a microbe, to the receptor, such as an antibody, distorts the liquid crystal, induces birefringence and thus causes the generation of detectable light (col. 6, lines 28-31). The spatial distortion caused by the formation of the antigen-antibody complex is transmitted to the contiguous liquid crystal (col. 6, lines 33-35). The method is performed in a multiwell system, wherein each well of the system would contain PDAs to a specific ligand, such as a pathogenic microbe, interfaced with an amplification mechanism of the present invention (col. 5, lines 58-64). When the microbial agent interacts with the antibody, the resulting antibody distortion triggers the amplification mechanism.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the detection of pathogen binding by liquid crystal material as taught by Woolverton et al. in the method of Albertí et al. One of ordinary skill in the art would have been motivated to include the detection of pathogen binding by liquid crystal material in the method of Albertí et al. for the advantage of providing a system that rapidly, reliably, and

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automatically detects ligands, especially when present in very small quantities and consequently provides a measurable signal (col. 1, lines 59-62). Since both Albertí et al. and Woolverton et al. disclose the method of pathogen binding (Albertí: pg. 4727, right col., lines 11-22; Woolverton: col. 6, lines 28-31).

### ***Response to Arguments***

17. Applicant's arguments in view of the rejection under 35 U.S.C. 102(e) of Claims 1, 3-7, 14 and 16 as being anticipated by Abbott et al. (US Patent 6,284,197 B1) filed on 3/6/03 have been fully considered but they are not persuasive.

Applicant contends that Abbott et al. fail to teach 1) providing a substrate that has depression; 2) any pathogen bound to the substrate "at least partially occupies the depression"; and 3) "substantially all the binding agent is located in the depressions of the detection region." Therefore, Abbott et al. do not anticipate the presently claimed invention.

It is the examiner position that Abbott et al. do anticipate the presently claimed invention. Abbott et al. do teach 1) providing a substrate that has depression; 2) any pathogen bound to the substrate "at least partially occupies the depression"; and 3) "substantially all the binding agent is located in the depressions of the detection region." Abbott et al. disclosed that *"this aspect of the present invention allows for the formation of devices of both simple planar and also more complex geometries (e.g., curved, cylindrical, sinusoidal). In a presently preferred embodiment, the substrate of the device is a mesh, for example a TEM grid. In this embodiment, the recognition moiety can be attached to the spaces between the mesh members (i.e., in wells) and the mesogenic layer is floated on the top of the substrate (col. 13, lines 32-39)."*

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct  
June 5, 2003.

  
PADMASHRI PONNALURI  
PRIMARY EXAMINER